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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,050	11/03/2006	Robert Graham Price	P2790/331252	8823

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EXAMINER	
GITOMER, RALPH J	
ART UNIT	PAPER NUMBER
1657	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,050	PRICE ET AL.	
	Examiner	Art Unit	
	Ralph Gitomer	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The preliminary amendment received 6/15/06 has been entered and claims 1-20 are currently pending in this application.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 14-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Richardson.

Richardson (5,221,606) entitled "Reagent and Kit for Enzyme Assay Comprising A Substrate Consonant with Given Enzyme to Be Assayed" teaches in column 1 last paragraph bridging to column 2, the chromogens are adsorbed onto filter paper or a membrane when are then an indicator of the presence or absence of a particular enzyme for dipstick devices. In column 11 enzyme substrates are selectively absorbed on to cellulose and related polymers giving intense colors which are not leached from the polymer by water. In line 43 the sample may be urine.

All the features of the claims are taught by Richardson for the same function as claimed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Richardson in view of Bochner.

See the teachings of Richardson above.

The device claims differ from Richardson in that they include a number of chromogenic enzyme substrates, Mg+2, buffer, layered filters.

Bochner (5,464,755) entitled “Microbiological Medium and Method of Assay” teaches in column 1 line 32 that urine is a type of sample tested. In column 7 lines 21-27, rapid tests include enzymatic assays, stains, and filtration that is colorimetric. In column 9 lines 16-37, selective media with multiple colorimetric substrates are listed. In column 13 last paragraph, urinary tract pathogens are plated on multiple compartment

dishes to distinguish various pathogens. In column 41 Example 15, Mg+2, a common enzyme cofactor is added to enhance enzyme activity.

It would have been obvious to one of ordinary skill in the art at the time of the invention to employ the device of Richardson and include any desired known selective substrates to identify bacteria because Richardson teaches identifying bacteria with chromogenic substrates and to then include any known or multiple chromogenic substrates for their known function as taught by Bochner with the expected results would have been obvious. Identifying bacteria on any type of substrate with known chromogens is old. Cellulosic filter paper has pores of many different sizes. And adding reagents known to preserve activity of bacterial enzymes desired to be detected as taught by Bochner would have been obvious. Filtering bacteria with buffers is old. Regarding layers, the filters of Richardson reads on layers as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

A reading of the specification reveals a device and method for determining the type of bacteria present in urine where the device has multiple filters each filter having different pore sizes to concentrate different bacteria on each filter and different multiple chromogenic substrates coated on the filters to identify types of bacteria in different regions. The references of record do not fairly suggest or teach this device or method. However, this has not been claimed.

There are a number of instances of lack of antecedent basis in the claims, for example in claim 1 line 1 "the characterization". In claim 1 “characterization of microorganisms” is unclear as to what sort characterization may be intended. In claim 8 line 2, “chosen from” is improper Markush terminology. In claim 10 “IPTG” should be spelled out in the first occurrence in the claims. In claim 12 “a 903 membrane” is queried, note that trademarked names are improper in claims. In claim 13 “a different filter” is not understood in context where no filters are seen. In claim 14(c) “leaving” is not a proper positively recited method step. And what the incubator may be set for is unclear. The last step of claim 14 does not accomplish the preamble of the claim, where “in order to ascertain the bacteria present” is not in any order and what is ascertained is not set forth.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The abstract of the disclosure is objected to because it does not describe the invention. Correction is required. See MPEP § 608.01(b).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Aoyama (JP 2001-321196) teaches a layered culture medium for detecting pathogens.

Lee (WO 02/33414) teaches multiple pathogen detection.

Thompson (5,096,668) teaches devices for determining bacteria.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/
Primary Examiner, Art Unit 1657

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